UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

ANGIE CRUZ, I.H., AR'ES KPAKA, and RIYA CHRISTIE, on behalf of themselves and all others similarly situated, Plaintiffs, v. HOWARD ZUCKER, as Commissioner of the Department of Health, Defendant.	14 Civ. 4456 (JSR) ORAL ARGUMENT SCHEDULED FOR SEPTEMBER 25, 2015

MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

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Plaintiffs Angie Cruz, Ar'es Kpaka, and Riya Christie, on behalf of themselves and all others similarly situated (the "Class"), respectfully submit this Memorandum of Law in Support of Plaintiffs' Motion for Summary Judgment.

PRELIMINARY STATEMENT

In 1998, the New York State Department of Health ("DOH") imposed a blanket ban on Medicaid coverage for the treatment of people diagnosed with gender identity disorder ("GID") or gender dysphoria ("GD"), depriving transgender New Yorkers of medically necessary care and exposing them to needless suffering. The ban, embodied in 18 N.Y.C.R.R. § 505.2(l), lacked scientific basis, was unsupported by experienced professionals, and had no economic purpose. Plaintiffs thus brought this action to put an end to the State's violation of its obligations under the Medicaid Act to its needy transgender citizens.

In response to this action, Defendant amended § 505.2(*l*) to lift the blanket ban on coverage, but left in place a number of restrictions on medically necessary care for GD, including prohibitions on coverage for transgender youth care and for certain procedures deemed "cosmetic" *per se*. In particular, § 505.2(*l*) still bars coverage for (i) a number of procedures that are medically necessary for some patients to successfully transition from one gender to another, (ii) surgeries involving sterilization for people under 21, (iii) surgeries for people under 18, whether involving sterilization or not, and (iv) hormone therapy for people under 18. These coverage exclusions cannot stand.

Under the Medicaid Act, it is unlawful to deny coverage (1) for medically necessary treatments falling within certain mandated coverage categories under the Availability Provision; (2) to patients with one diagnosis while providing coverage to patients with other diagnoses under the Comparability Provision; (3) for medically necessary treatments for patients under 21, under EPSDT. But that is exactly what DOH has done here.

As the record unequivocally shows, there is no dispute that each of the excluded procedures is medically necessary for some patients with GD, covered by New York Medicaid for enrollees diagnosed with conditions other than GD, made available to those over the age of 21, and generally accepted by the professional medical community as effective and proven to treat GD. The Court should therefore grant summary judgment on Plaintiffs' First, Second, and Sixth Claims for Relief because Plaintiffs are entitled to judgment as a matter of law.

BACKGROUND

I. COVERAGE FOR TRANSGENDER CARE AND AMENDING § 505.2(*l*).

Prior to the enactment of 18 N.Y.C.R.R. § 505.2(*l*) in 1998, New York provided coverage for gender reassignment surgery ("GRS") and related care for GD. (¶ 2.)[1] There is no evidence to suggest that coverage for this treatment was cost-prohibitive prior to 1998, nor that DOH considered the treatments to be experimental. (¶¶ 14, 15-22.) Nevertheless, in response to a demand by Governor Pataki, DOH promulgated § 505.2(*l*), which imposed a blanket ban on Medicaid coverage for GRS and related care. (¶¶ 3-4.) In seeking to justify that abrupt about-face, DOH claimed that GRS had "not been proven to be safe and effective over the long-term." (¶ 13.) But that was not true: public comments submitted in response to § 505.2(*l*)'s notice of proposed rulemaking made clear that practitioners viewed these treatments as safe, effective, and necessary (¶¶ 15-17), and DOH's own medical consultant, Dr. Richard Propp, concurred that GRS was safe and effective. (¶ 18-22.) Nevertheless, aware that "[t]he governors office [did] not want to pay for it," DOH conferred with a different medical consultant, Dr. Harvey Bernard, who approved DOH's predetermined conclusion. (¶¶ 23-25.)

Following its enactment, § 505.2(*l*) was subject to mandatory review every five years

[1] Citations to "¶" refer to paragraphs in Plaintiffs' Statement of Undisputed Material Facts Pursuant to Local Civil Rule 56.1, dated August 28, 2015.

pursuant to § 207 of the New York State Administrative Procedure Act ("SAPA"), to determine whether or not the regulation should be modified. (¶ 26.) DOH's determination was required to be published in the New York State Register, subject to public comment, and those comments were subject to assessment. See SAPA § 207(3), (4); (¶¶ 27-28). DOH, however, did not comply. Indeed, as recently as 2013, DOH did nothing to review § 505.2(*l*) because "the Commissioner had already weighed in on coverage and said that Medicaid was not going to cover transgender services." (¶ 31.) Nevertheless, the notice of re-adoption published in the State Register that year attracted approximately 140 public comments, and there is no evidence that any were in favor of re-adoption. (¶¶ 33.) But those comments fell on deaf ears. DOH never bothered to assess them, and left the regulation intact.[2] Thus, for 17 years, DOH failed to cover necessary medical care for the treatment of GD, without an adequate scientific basis for doing so and in contravention of its administrative duties. (¶¶ 2-22, 25-36.)

All that changed in 2014, when Plaintiffs commenced this lawsuit, challenging DOH's refusal to provide medically necessary care required by federal law. Shortly after the complaint was filed, DOH and the Governor's office took sudden interest in the subject, claiming they wished to settle the case and amend § 505.2(*l*). (¶ 37.) But in their haste to moot the litigation, DOH engaged in a "rushed" process that was deeply flawed. (¶ 58.) No one at DOH has any expertise in treating GID/GD. (¶ 63.) No one at DOH consulted practitioners who did have any such expertise, nor did they reach out to any professional organizations who did. (¶ 62.) Nor did DOH hold any public hearings for experts or the public to voice any concerns about the proposed regulation. (¶ 64.) Instead, DOH employees conducted their own superficial and misguided assessment of the treatments for GID/GD, misinterpreting certain sources, while discounting

[2] This is the only instance DOH can recall when it failed to assess public comments. (¶¶ 34, 36.)

others as "inherent[ly] bias[ed]." (¶¶ 100-01.)

DOH relied almost exclusively on reports produced by Hayes, Inc. ("Hayes") and the Oregon Health and Science University ("OHSU"). (¶¶ 71, 76.) Neither Hayes nor OHSU have any expertise in the treatment of GID/GD. (¶¶ 72, 79.) The OHSU report merely aggregated information about what treatments other payers cover—it gave no indication of the medical necessity of any such treatment. (¶¶ 73-75.) Likewise, the Hayes reports merely aggregated and assessed the quality of research on GID/GD; the reports did not offer any opinion on whether treatments were medically necessary either. (¶¶ 77-78, 80.)

On March 11, 2015, DOH amended § 505.2(*l*) to lift the blanket ban on coverage. (¶¶ 37-38, 56.) However, even as amended, § 505.2(*l*) continues to exclude coverage for the following medically necessary care for GD: treatments that DOH has deemed to be "cosmetic"; GRS for individuals under 21 that results in sterilization; GRS for individuals under 18; and hormone therapy for people under 18. (¶¶ 39-40.)

II. THE AMENDED REGULATION.

A. § 505.2(*l*) Bars Coverage For Procedures Deemed "Cosmetic."

The Amended § 505.2(*l*) plainly states that "**Payment will not be made**" for certain specified services and procedures, namely:

> cosmetic surgery, services, and procedures, including but not limited to: (a) abdominoplasty, blepharoplasty, neck tightening, or removal of redundant skin; (b) breast augmentation; (c) breast, brow, face, or forehead lifts; (d) calf, check, chin, nose, or pectoral implants; (e) collagen injections; (f) drugs to promote hair growth or loss; (g) electrolysis, unless required for vaginoplasty; (h) facial bone reconstruction, reduction, or sculpting, including jaw shortening and rhinoplasty; (i) hair transplantation; (j) lip reduction; (k) liposuction; (l) thyroid chondroplasty; and (m) voice therapy, voice lessons, or voice modification surgery.

18 N.Y.C.R.R. § 505.2(*l*)(4)(v) (emphasis added) (the "Deemed Cosmetic Procedures"). These

procedures are covered for diagnoses other than GD, and are medically necessary to treat GD for some people. (¶¶ 125, 132-34, 137-38, 140, 142-45, 147-48, 153-55, 170-71.)

Contemporaneous communications among policy-making staff at DOH confirm that, current litigation posturing notwithstanding, DOH intended the amended § 505.2(*l*) to mean exactly what it says: no coverage for the Deemed Cosmetic Procedures to treat GD. For instance, before the amendment became effective, the procedures were referred to as "non-covered" (¶ 105); draft proposals that would have provided coverage for the Deemed Cosmetic Procedures, were rejected (¶¶ 106-09), with one staff member even expressing concern that an alternative definition would actually result in payment for the procedures (¶ 107); cost estimates for the procedures covered by the amended § 505.2(*l*) did not include any estimate of the Deemed Cosmetic Procedures (¶¶ 112, 114); and revisions to the draft regulation proposed by Plaintiffs that would have made clear that the Deemed Cosmetic Procedures were covered were rejected by DOH out of hand (¶¶ 110-11). After the amendment was enacted, DOH's position on the meaning of § 505.2(*l*) did not change; in response to questions from enrollees, plans, and providers, DOH confirmed the Deemed Cosmetic Procedures were not covered. (¶¶ 116-21.) And, in March 2015, DOH published a "Medicaid Update" (the "March Guidance"), in which it reiterated that "Payment will not be made" for the Deemed Cosmetic Procedures. (¶ 115.)[3]

The Deemed Cosmetic Procedures are in fact medically necessary for some individuals, as DOH has admitted. (¶¶125, 132-34, 137-38, 140, 142, 145.) The procedures are not

[3] In June, DOH issued a new Medicaid Update article that purported to "supersede" the March Guidance, asserting that "Payment will not be made for any procedures that are performed solely for the purpose of improving an individual's appearance. The following procedures will be presumed to be performed solely for the purpose of improving appearance and will not be covered, unless justification of medical necessity is provided and prior authorization is received: [the Deemed Cosmetic Procedures]" (the "June Guidance"). (¶ 123.) The June Guidance was published as a purely tactical maneuver in response to developments in this case and was not, among other things, issued in accordance with SAPA. The Court should therefore disregard it.

prescribed to make someone more attractive; they are prescribed to conform someone's body with their gender identity, which requires, in certain cases, more than just genital and/or chest surgery. (¶¶ 132-36.) As Plaintiffs' experts have described, this is an effective and necessary form of treatment. (¶¶ 130-37, 139-48.) The leading expert guidelines on GD care also confirm the medical necessity of these procedures in some cases. (¶¶ 102-04, 143.)

Additionally, although New York covers the Deemed Cosmetic Procedures to treat other diagnoses, no coverage is available for these same procedures to treat GD. (¶¶ 115-21, 153-55.)

B. § 505.2(*l*) Bars Coverage For Medically Necessary Breast Augmentations.

New York provides Medicaid coverage for breast augmentation to treat diagnoses other than GD, including to treat breast cancer patients who have undergone mastectomies. (¶ 175.) But DOH treats people with GD differently. The March Guidance and the June Guidance provide, in pertinent part, that breast augmentation will only be covered when "[t]he patient has completed a minimum of 24 months of hormone therapy during which time no breast growth has occurred." (¶ 157 (emphasis in original).) In crafting this policy, DOH relied on studies that showed that there will always be *some* breast growth after a course of hormone therapy, but often not enough to alleviate distress caused by GD. (¶¶ 158-61.) DOH's prerequisites are therefore impossible for anyone to meet, making the potential for coverage a mere ruse.

In setting that unattainable threshold, DOH misconstrued (or at least misunderstood) the expert guidelines it reviewed. The Endocrine Society is a leading organization for research on hormones and clinical endocrine practice. (¶¶ 95-98.) The Endocrine Society's guidelines on the treatment of transsexual persons[4] indicate that breast growth generally maximizes after 2 years of hormone therapy, and in no way suggest that a patient not undergo breast augmentation

[4] *Endocrine Treatment of Transsexual Persons: An Endocrine Society Clinical Practice Guideline*, September 2009 (the "Guidelines").

if hormone therapy results in some breast growth. (¶¶ 166, 168-70.) Rather, the Guidelines recommend undergoing a course of hormone therapy so that a patient may see how much breast growth develops before augmenting the growth through surgery. (¶ 166.) Similarly, the World Professional Association for Transgender Health ("WPATH"), the world's leader on best practices for transgender healthcare, publishes "Standards of Care"[5] that recommend undergoing a course of hormone therapy to improve surgical results. Like the Guidelines, the SOC in no way recommend that hormone therapy should be a bar to breast augmentation. (¶ 165.) Plaintiffs' unrebutted experts further establish that breast augmentation is medically necessary for some individuals even when hormone therapy produces some breast growth. (¶¶ 171-74.)

C. § 505.2(*l*) Bars Coverage For Medically Necessary Surgeries.

Surgeries resulting in sterilization to treat GD are medically necessary for some individuals under 21, and are available for diagnoses other than GD. (¶¶ 179-80, 188.) Yet, § 505.2(*l*) bars coverage for these surgeries. (¶ 176.) In response to public comments opposing this restriction, Defendant asserted that there is a federal bar on sterilizing surgeries for people under 21 that New York was bound to apply. (¶¶ 48, 177.) But DOH's interpretation of federal law was wrong, as it now concedes. (¶¶ 178, 181.) According to the Centers for Medicare and Medicaid Services ("CMS"), the 21-year-old restriction only applies where the primary purpose is sterilization, not, as with GRS, where sterilization is incident to surgery. (¶¶ 178.) Although DOH represented that it would amend § 505.2(*l*) if its interpretation of federal law was wrong, and despite CMS informing DOH of the correct interpretation four months ago, DOH has done nothing to correct its error and provide coverage for this necessary care. (¶¶ 177-78, 181.)

Surgeries to treat GD are also medically necessary for some people under 18, and are available for diagnoses other than GD. (¶¶ 184-88.) Yet § 505.2(*l*) bars all such surgeries for

[5] WPATH *Standards of Care and Ethical Guidelines* (the "SOC").

people under 18, without exception. (¶¶ 38-39, 182.) DOH imposed this restriction on the basis that 18 is the age of majority and consent in New York. (¶ 182.) But this ignores that parents can, and often do, provide consent for surgeries on behalf of their children with respect to other diagnoses. (¶ 183.)

D. Section 505.2(*l*) Bars Coverage For Medically Necessary Hormone Therapy.

Pubertal suppressants, a form of hormone therapy, are considered medically necessary to treat adolescents with GD. (¶¶ 190-94, 202-03.) These medications are prescribed once patients reach a particular stage of puberty, called Tanner Stage 2, to delay puberty and alleviate the distress associated with developing undesired sex characteristics and an outward appearance contrary to one's true gender identity. (¶ 205.) Pubertal suppressants are used until a patient reaches an appropriate stage to receive cross-sex hormones, if necessary. (¶ 199.) The availability of pubertal suppressants is therefore critical to treating adolescents with GD, and can help avoid the need for certain surgeries later in life that would otherwise be necessary to correct undesired physical changes caused by experiencing the incorrect puberty. (¶¶ 191-94, 202-03.) DOH witnesses agree that pubertal suppressants are medically necessary to treat some adolescents with GD. (¶ 210.) Moreover, New York Medicaid covers pubertal suppressants to treat diagnoses other than GD, including precocious puberty and endometriosis. (¶ 211.)

Cross-sex hormones are also medically necessary to treat GD in certain individuals under 18. (¶¶ 199, 212-13.) Cross-sex hormones are used to allow the youth to go through pubertal development of their target gender. (¶ 214.) DOH witnesses concede that cross-sex hormones are medically necessary to treat some people with GD under 18. (¶ 213.) And Medicaid coverage is available for cross-sex hormones to treat diagnoses other than GD. (¶ 222.)

The use of pubertal suppressants and cross-sex hormones to treat people under 18 with GD is generally accepted among practitioners as safe, effective, and proven, and their

recommended use is reflected in expert guidelines. (¶¶ 195-99, 204, 209-10.) These treatments have been used to treat youth with GD for over 25 years abroad, and at least a decade in the United States. (¶ 196.)

Nevertheless, DOH determined to bar coverage for hormone therapy to treat GD in people under 18. (¶¶ 39, 190.) New York allegedly has a "policy" to only cover drugs for uses that have been either FDA-approved or that are supported in certain medical compendia listed in federal regulations, and use of hormone therapy to treat GD in people under 18 meets neither of these requirements. (¶¶ 222-23.) DOH concedes, however, that this "policy" is permissive, not mandatory (¶¶ 224), and there is no evidence that the "policy" has been applied consistently to all drugs. (See ¶ 225.)

ARGUMENT

Summary judgment should be granted when the court determines that "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). "[T]he mere existence of *some* alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no *genuine* issue of *material* fact." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247-48 (1986) (emphasis in original). "Only disputes over 'facts that might affect the outcome of the suit under the governing law' will preclude a grant of summary judgment." Sheet Metal Workers' Nat'l Pension Fund v. Maximum Metal Mfrs. Inc., No. 13-cv-7741, 2015 WL 4935116, at *2 (S.D.N.Y. Aug. 18, 2015) (quoting Anderson, 477 U.S. at 248).

The standard for granting summary judgment is not altered by the fact that Plaintiffs challenge a state regulation. A state agency's interpretation of federal law in promulgating a regulation is not entitled to deference by a federal court, at summary judgment or otherwise. See Turner v. Perales, 869 F.2d 140, 141 (2d Cir. 1989) (distinguishing state agency review of

federal law from Chevron deference); DeLuca v. Hammons, 927 F. Supp. 132, 133 (S.D.N.Y. 1996) (same). Accordingly, whether § 505.2(*l*) violates federal law is an "issue of law, subject to *de novo* review in federal court." Turner, 869 F.2d at 141; DeLuca, 927 F. Supp. at 133; see also Orthopaedic Hosp. v. Belshe, 103 F.3d 1491, 1495 (9th Cir. 1997).

I. THE COURT SHOULD GRANT SUMMARY JUDGMENT ON PLAINTIFFS' FIRST CLAIM FOR RELIEF UNDER THE AVAILABILITY PROVISION.

Section 1396a(a)(10)(A) of title 42, the "Availability Provision" of the Medicaid Act, mandates that a state "must" "provide for making medical assistance available, including at least the care and services listed in paragraphs (1) through (5), (17), (21), and (28) of section 1396d(a) of this title, to all individuals" who meet certain Medicaid eligibility criteria. 42 U.S.C. § 1396a(a)(10)(A). Because the undisputed facts demonstrate that Defendant presently prohibits coverage for necessary medical assistance required to be covered by Medicaid under this provision, summary judgment on Plaintiffs' First Claim for Relief should be granted.

A. The Legal Framework For Medicaid Coverage.

1. States Must Provide Coverage for Medically Necessary Treatments Falling Within the Mandatory Categories.

Title XIX of the Social Security Act of 1965 establishes the Medicaid program, 42 U.S.C. §§ 1396 et seq., for "the purpose of enabling each State, as far as practicable under the conditions in such State, to furnish . . . medical assistance [to persons] whose income and resources are insufficient to meet the costs of *necessary medical services*." 42 U.S.C. § 1396-1 (emphasis added). Once a state chooses to participate in Medicaid, the state "must implement and operate [a] Medicaid program[] that compl[ies] with detailed federally mandated standards." Cruz v. Zucker, __ F. Supp. 3d __, 2015 WL 4548162, at *3 (S.D.N.Y. July 29, 2015) (quoting Cmty. Health Care Ass'n of N.Y. v. Shah, 770 F.3d 129, 135 (2d Cir. 2014)).

Section 1396d(a) lists 29 categories of coverage – eight mandatory, the rest optional.

States *must* provide coverage for the mandatory categories of treatment, including physician's services and inpatient and outpatient hospital services. See 42 U.S.C. §§ 1396a(a)(10)(A), 1396d(a)(1), (2), (5). And states must cover medically necessary treatments that fall within the scope of the mandatory categories. See, e.g., Pinneke v. Preisser, 623 F.2d 546, 549 (8th Cir. 1980) ("basic categories of medical assistance [must] be provided to all categorically needy persons when the assistance is medically necessary."); Moore ex rel. Moore v. Reese, 637 F.3d 1220, 1233 (11th Cir. 2011); Hern v. Beye, 57 F.3d 906, 911 (10th Cir. 1995) ("This circuit, as well as several other courts, has interpreted Title XIX and its accompanying regulations as imposing a general obligation on states to fund those mandatory coverage services that are medically necessary."); Dexter v. Kirschner, 984 F.2d 979, 983 (9th Cir. 1992) (states "must provide assistance to pay for *medically necessary* inpatient hospital and physician's services.")

2. A State Cannot Place Total Bans on Medically Necessary Treatment.

A state must provide services that are "sufficient in amount, duration, and scope to reasonably achieve [their] purpose," and cannot "arbitrarily deny or reduce the amount, duration, or scope of a required service . . . solely because of the diagnosis, type of illness, or condition." 42 C.F.R. § 440.230(b), (c). As a result, limits must be "appropriate[,] . . . based on such criteria as medical necessity or on utilization control procedures." Id. § 440.230(d). Utilization control procedures include "'prior authorization processes, or similarly designed processes, to control access, prevent fraud, or streamline efficiency,' or 'resources to determine the medical necessity of a procedure.'" Davis v. Shah, No. 12-cv-6134, 2013 WL 6451176, at *12 (W.D.N.Y. Dec. 9, 2013), appeal argued, No. 14-543 (2d Cir. Jan. 5, 2015) (quoting Bontrager v. Indiana Fam. & Soc. Servs. Admin., 697 F.3d 604, 610-11 (7th Cir. 2012)).

Also, although states may reasonably define medical necessity, a treatment that meets that definition and is in a mandatory category must be covered. See Pinneke, 623 F.2d at 550

(ordering coverage of medically necessary GRS). New York has defined medical necessity as anything "necessary to prevent, diagnose, correct or cure conditions in the person that cause acute suffering, endanger life, result in illness or infirmity, interfere with such person's capacity for normal activity, or threaten some significant handicap." N.Y. Soc. Servs. L. § 365-a(2).

Definitions of medical necessity do not, however, "remove from the private physician the primary responsibility of determining what treatment should be available to his patients," but merely establish "that the physician is required to operate within such reasonable limitations as the state may impose." Rush v. Parham, 625 F.2d 1150, 1156 (5th Cir. 1980) (noting that Medicaid "is centered around the judgment of the private physician."); see also Pinneke, 623 F.2d at 549-50 & n.3 (medical necessity "rests with the individual recipient's physician and not with clerical personnel or government officials"). Indeed, Medicaid "create[s] a presumption in favor of the medical judgment of the attending physician in determining the medical necessity of treatment." Weaver v. Reagen, 886 F.2d 194, 200 (8th Cir. 1989). New York's Medicaid regulations are consistent with this understanding and mandate that, in the context of prior approval, a practitioner's professional expertise "is entitled to significant weight in reaching a determination and cannot be outweighed solely by the opinions of non-medical personnel or persons not within the same medical profession as the ordering or treating practitioner." 18 N.Y.C.R.R. § 513.6(e).

The Medicaid regime thus distinguishes between reasonable limits on covered treatments and outright bans on medically necessary treatments for particular diagnoses. A state may do the former, but cannot do the latter. See Pinneke, 623 F.2d at 549 (creation of an "irrebuttable presumption" that procedure "can never be medically necessary" is invalid); Hern, 57 F.3d at 911 ("a state law that categorically denies coverage for a specific, medically necessary procedure

except in those rare instances when the patient's life is at stake . . . contravenes the purposes of Title IX"); White v. Beal, 555 F.2d 1146, 1151 (3d Cir. 1977) ("We find nothing in the federal statute that permits discrimination based upon etiology rather than need for the service.").

B. The Deemed Cosmetic Procedures Are Mandatory Treatments That Are Barred By § 505.2(*l*) Even When Medically Necessary.

1. The Deemed Cosmetic Procedures Are Mandatory and Medically Necessary for Some Individuals.

All of the Deemed Cosmetic Procedures, except drugs to promote hair growth or loss, fall within the mandatory categories of either physician's services, inpatient services, or outpatient services. Compare ¶ 40 with 42 U.S.C. § 1396d(a)(1), (2), (5). Because those procedures are "mandatory," they *must* be covered when medically necessary. See, e.g., Pinneke, 623 F.2d at 549; Moore, 637 F.3d at 1233; Hern, 57 F.3d at 911; Dexter, 984 F.2d at 983.

Unrebutted expert evidence establishes that these procedures are medically necessary for some people. (¶¶ 130-37, 139-48.) DOH has admitted the necessity of these procedures through testimony of its designated representative (and other DOH witnesses), and Defendant is bound thereby. (¶¶ 106, 125, 138; McNamara Decl. Ex. 57 (Tr. of 8/12/15 Conference) (explaining that 30(b)(6) witness's testimony "will be binding on the state agency as a whole").) Because there is no genuine issue of material fact, summary judgment on the Deemed Cosmetic Procedures should be granted. See Hayden v. Paul, Weiss, Rifkind, Wharton & Garrison LLP, 955 F. Supp. 248, 259 (S.D.N.Y. 1997) (granting summary judgment where facts not "subject to rational dispute").

2. Section 505.2(*l*) Excludes Coverage for the Deemed Cosmetic Procedures Even When Medically Necessary.

DOH appears to believe it is immune from liability for violating federal law because, after the Court denied Defendant's motion to dismiss, DOH issued the June Guidance, which

purports to "supersede" the March Guidance and extend coverage for the Deemed Cosmetic Procedures that were previously barred. DOH is wrong. Because the Court has already interpreted § 505.2(*l*) to exclude coverage of the Deemed Cosmetic Procedures as a matter of law on its face, that interpretation is the law of the case, and cannot be disturbed.

The law of the case doctrine "posits that when a court decides upon a rule of law, that decision should continue to govern the same issues in subsequent stages in the same case." Arizona v. California, 460 U.S. 605, 618 (1983), decision supplemented, 466 U.S. 144 (1984). This doctrine represents "a practice of courts generally not to reconsider that which has already been decided." Rezzonico v. H & R Block, Inc., 182 F.3d 144, 149 (2d Cir. 1999). This doctrine applies in cases like this where a court has previously determined the meaning of an unambiguous instrument. Frito-Lay, Inc. v. Bachman Co., 704 F. Supp. 432, 438 (S.D.N.Y. 1989) (on summary judgment, court's ruling on earlier motion regarding meaning of statute's plain language was law of the case); State Farm Mut. Auto. Ins. Co. v. Mallela, No. CV-00-4923 (CPS), 2002 WL 31946762, at *16 (E.D.N.Y. Nov. 21, 2002) (court's ruling on earlier motion interpreting New York State no-fault insurance regulations was law of the case).

The law of the case doctrine is squarely applicable here because § 505.2(*l*) is clear that it "by its plain terms, excludes coverage for the procedures deemed 'cosmetic.'" Cruz, 2015 WL at *13. The June Guidance does not change this. First, to the extent DOH argues that the June Guidance represents its interpretation of the regulation, that interpretation is entitled to no deference because the regulation is unambiguous, as the Court has held. See Restrepo v. McElroy, 369 F.3d 627, 639 n.19 (2d Cir. 2004) (deference to agency interpretation "warranted only when the language of the regulation is ambiguous"). Deference is also unwarranted where (i) an interpretation "conflicts with a prior interpretation," as the June Guidance conflicts with

the March Guidance, Christopher v. SmithKline Beecham Corp., 132 S. Ct. 2156, 2166 (2012), and (ii) the interpretation is nothing more than a post-hoc litigation tactic, id. (no deference when interpretation is "nothing more than a convenient litigating position . . . or a post hoc rationalization . . . to defend past agency action against attack"). (See ¶¶ 124, 126-27.)

Moreover, to the extent the June Guidance is meant to be a new rule, it is invalid under New York law, which requires that such rules go through the SAPA process. SAPA §§ 102(2)(a)(i), 202; Destiny USA Dev., LLC v. New York State Dep't of Envtl. Conservation, 879 N.Y.S.2d 865, 868 (N.Y. App. Div. 2009) (agencies may not legislate through "guidance"); Yaretsky v. Blum, 456 F. Supp. 653, 656-57 (S.D.N.Y. 1978) (agency "memoranda" that "significantly affect the rights of the public" did not meet exception to SAPA rulemaking requirement). The Court's legal construction of § 505.2(*l*) therefore stands.[6]

There is no genuine issue of material fact that the Deemed Cosmetic Procedures are medically necessary mandatory treatments for which § 505.2(*l*) bars coverage, and summary judgment should therefore be granted to Plaintiffs with respect to these treatments.

3. The June Guidance Bars Coverage for Breast Augmentations.

Breast augmentation is among the mandatory services that must be covered when medically necessary. See 42 U.S.C. § 1396d(a)(1), (2), (5). Under the plain terms of § 505.2(*l*) and the March Guidance, however, Medicaid coverage for breast augmentation is not available to treat GD, even if medically necessary. Specifically, the Guidance states that there will be no coverage for breast augmentation unless 24 months of hormone therapy has resulted in no breast growth. (¶ 157.) Studies show, however, that any transgender person who takes feminizing

[6] Plaintiffs understand that Defendant has moved the Court for reconsideration of the Court's decision on Defendant's motion to dismiss with respect to the Court's holding that § 505.2(*l*) prohibits coverage for the Deemed Cosmetic Procedures. Plaintiffs' opposition to the motion for reconsideration will establish why that motion should be denied.

hormone therapy for 24 months will experience at least some breast growth. (¶¶ 158-59.) DOH was well aware of these studies, and crafted the policy to shield itself from having to provide coverage for this procedure. (¶ 158-62.) In fact, the policy even contravenes instructions from the Governor's office, which believed non-coverage of breast augmentation to be "untenable." (¶ 156.)

In any case, it is undisputed that breast augmentation is medically necessary for some individuals who do experience some breast growth after undergoing 24 months of hormone therapy. (¶¶ 161, 164, 170-72.) Defendant's policy here flips the medical community's guidance on its head. The medical community recommends taking hormone therapy to better the results of breast augmentation surgery, not as a way to avoid breast augmentation. Plaintiffs' expert Dr. Olson testified that she recommends at least a year of hormone therapy before surgery so that a patient is aware of how much natural breast growth has occurred before adding to it through surgery. (¶ 173.) The WPATH SOC similarly recommend a course of hormone therapy beforehand to improve the results of breast augmentation. (¶ 164-65.) Accordingly, because this exclusion violates the Medicaid Act, summary judgment in Plaintiffs' favor should be granted.

C. Section 505.2(*l*) Denies Coverage For Medically Necessary Mandatory Treatments To People Under 21 And Under 18.

The Medicaid Act's requirement that states provide coverage of any medically necessary, mandatory treatments to Medicaid recipients applies regardless of the patient's age. Despite that requirement, § 505.2(*l*) imposes certain impermissible restrictions based on age. In particular, it bars coverage of (i) surgeries that result in sterilization for individuals under 21, and (ii) *all* surgeries for individuals under 18, notwithstanding whether such treatments may be medically necessary for patients who do not meet those age requirements. Summary judgment for Plaintiffs is warranted because there is no genuine issue of material fact that GRS involving

sterilization is medically necessary for some patients under 21, and various forms of surgical intervention are medically necessary to treat GD in some people under 18.

The unrebutted expert evidence shows that GRS involving sterilization is medically necessary to treat some people under 21 who have GD. (¶¶ 179.) Defendant, through binding Rule 30(b)(6) testimony, has admitted this. (¶ 180.) Defendant's sole rationale for this restriction was that federal regulations required it, but as Defendant has also conceded, that interpretation of federal law was wrong, and § 505.2(*l*) must be changed to eliminate this restriction. (¶¶ 177-78, 181.)

The undisputed evidence also shows that genital surgery and other surgical treatments – including chest surgery – are medically necessary for certain people under 18. (¶¶ 184-87.)

Because there is no genuine issue as to either of these material facts, the imposition of age restrictions on these mandatory medically necessary treatments violates the Medicaid Act, and summary judgment in Plaintiffs' favor should be granted.[7]

II. THE COURT SHOULD GRANT SUMMARY JUDGMENT ON PLAINTIFFS' SECOND CLAIM FOR RELIEF UNDER THE COMPARABILITY PROVISION.

In passing the Medicaid Act, Congress intended "that the states may not blithely provide services to some of their needy residents while denying the same services to others who are equally needy." Cruz, 2015 WL at *10. Section 1396a(a)(10)(B), the "Comparability Provision," thus mandates that "medical assistance made available to any individual described in subparagraph (A) – (i) shall not be less in amount, duration, or scope than the medical assistance made available to any other such individual, and (ii) shall not be less in amount, duration, or scope than the medical assistance made available to individuals not described in subparagraph

[7] Section 505.2(*l*) also prohibits coverage of hormone therapy for people under 18. Such hormone therapy is mandatory insofar as it falls under the EPSDT provision. This set of treatments is therefore discussed in the EPSDT section below.

(A)." 42 U.S.C. § 1396a(a)(10)(B). This provision "precludes states from discriminating against or among the categorically needy," "applies equally to mandatory and optional medical services," Lankford v. Sherman, 451 F.3d 496, 505 (8th Cir. 2006), and governs "situations where the same benefit is funded for some recipients but not others," Rodriguez v. City of New York, 197 F.3d 611, 615-16 (2d Cir. 1999).

Section 505.2(*l*) violates the Comparability Provision in three ways.

First, § 505.2(*l*) violates the Comparability Provision because it denies coverage of the Deemed Cosmetic Procedures for people with GD, while extending coverage of those same procedures to people with other diagnoses. In New York, covered surgical procedures are listed in 18 N.Y.C.R.R. § 533.5 and the Physician Manual (published by DOH), which provides physicians with billing codes for all covered procedures to enable reimbursement. (¶¶ 154, 188.) If a given procedure has an associated billing code, New York Medicaid covers it; if there is no billing code, it is not covered. (¶ 154.) DOH witnesses have conceded that these procedures are covered for non-GD purposes. (¶¶ 153, 175.) For example, that breast augmentation is covered for individuals with breast cancer after undergoing mastectomy. (¶¶ 175.) Those same procedures, however, are not covered for the treatment of GD.

Second, § 505.2(*l*) violates the Comparability Provision by denying coverage for hormone therapy for people under 18 with GD, while providing that same treatment to patients diagnosed with other conditions. Specifically, New York provides coverage of pubertal suppressants for people under 18 who are diagnosed with precocious puberty or endometriosis. (¶ 211.) And coverage for hormones for people under 18 for diagnoses other than GD is also available. (¶ 221.)

Third and for the same reasons, § 505.2(*l*) violates the Medicaid Act by denying coverage

for procedures used in surgeries to treat people with GD under 21 and under 18, while covering those same procedures for people under 21 and under 18 for diagnoses other than GD. (¶ 188.)

In sum, because there is no genuine dispute of material fact that New York covers the Deemed Cosmetic Procedures, youth hormone therapy, and youth surgeries to treat diagnoses other than for GD, § 505.2(*l*) violates the Comparability Provision and cannot stand. Rodriguez, 197 F.3d at 615; Davis, 2013 WL at*12 (Comparability Provision violated where compression stockings available to treat some diagnoses, but not others). Summary judgment for Plaintiffs is thus appropriate.

III. THE COURT SHOULD GRANT SUMMARY JUDGMENT ON PLAINTIFFS' SIXTH CLAIM FOR RELIEF UNDER EPSDT.

"In 1989, Congress amended the Medicaid Act to broaden the categories of services that participating states must provide to Medicaid-eligible children. The 1989 Amendment mandates that participating states provide EPSDT services to all Medicaid-eligible persons under the age of 21." Moore, 637 F.3d at 1233; see 42 U.S.C. § 1396a(a)(43). The Early and Periodic Screening, Diagnostic, and Treatment Provision ("EPSDT") requires states to cover medically necessary treatment for people under 21, regardless of whether such treatment is covered for people over 21. Because GRS and hormone therapy are medically necessary for some people under 18, or 21, as the case may be, § 505.2(*l*) runs afoul of EPSDT and is therefore invalid.

A. EPSDT Mandates Coverage Of Medically Necessary Procedures For People Under 21.

EPSDT requires states to provide "early and periodic screening, diagnostic, and treatment services" to Medicaid recipients under 21. 42 U.S.C. §§ 1396a(a)(43), 1396d(r). States therefore *must* provide, *inter alia*, screening services (at regular intervals, but also whenever medically necessary) and "[s]uch other *necessary* health care, diagnostic services, treatment and other measures described in [42 U.S.C. § 1396d(a)] to correct or ameliorate defects and physical

and mental illnesses and conditions discovered by the screening services, *whether or not such services are covered under the State plan*." Id. § 1396d(r)(1), (5) (emphasis added).

"[E]very Circuit which has examined the scope of the EPSDT program has recognized that states must cover every type of health care or service [medically] necessary for EPSDT corrective or ameliorative purposes that is allowable under § 1396d(a)." S.D. ex rel. Dickson v. Hood, 391 F.3d 581, 590 (5th Cir. 2004); see Katie A., ex rel. Ludin v. Los Angeles Cnty., 481 F.3d 1150, 1154 (9th Cir. 2007) ("Although states have the option of providing certain 'optional' services listed in § 1396d(a) to other populations, they must provide all of the services listed in § 1396d(a) to eligible children when such services are medically necessary.").[8] The EPSDT's legislative history further establishes its expansive requirements to provide medically necessary care to individuals under 21 regardless of whether the care is provided to those over 21. See S.D., 391 F.3d at 589-92 (describing legislative history).[9]

The screening requirement is broadly construed so as not to serve as a bar to medically necessary treatment. Thus, to ensure the widest possible coverage for people under 21, any physician's examination can qualify as an interperiodic screening. See EPSDT Guide at 6 ("any visit or contact with a qualified medical professional is sufficient to satisfy EPSDT's screening

[8] See also Parents' League for Effective Autism Servs. v. Jones-Kelley, 339 Fed. App'x 542, 547 (6th Cir. 2009); Collins v. Hamilton, 349 F.3d 371, 376 n.8 (7th Cir. 2003); Pediatric Specialty Care, Inc. v. Ark. Dep't of Human Servs., 293 F.3d 472, 480 (8th Cir. 2002); Pittman v. Sec'y, Fla. Dep't of Health & Rehab. Servs., 998 F.2d 887, 889 (11th Cir. 1993); Dajour B. v. City of N.Y., No. 00-cv-2044, 2001 WL 830674, at *9 (S.D.N.Y. July 23, 2001); John B. v. Menke, 176 F. Supp. 2d 786, 800 (M.D. Tenn. 2001).

[9] CMS also interprets EPSDT to require coverage of medically necessary treatment, regardless of whether a state provides coverage for such treatment for adults. See *EPSDT – A Guide for States* at 10, CMS (June 2014), available at http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Early-and-Periodic-Screening-Diagnostic-and-Treatment.html (the "EPSDT Guide"). This is in accord with one of the goals of EPSDT to ensure that "children's health problems should be addressed before they become advanced and treatment is more difficult and costly." Id. at 1.

requirement"); DEP'T OF HEALTH & HUMAN SERVS. HEALTHCARE FIN. ADMIN., SMDL #01-006, Olmstead Update #4: HFCA Update (Jan. 10, 2001), at 10 ("we have long considered any encounter with a health care professional . . . inter-periodic screening"); see also HCFA PROGRAM ISSUANCE TRANSMITTAL NOTICE, REGION IV (MCD-78-92) (Oct. 7, 1992) ("Any physician encounter is potentially an interperiodic screen.").

B. New York Has Little Ability To Limit EPSDT Care.

The services covered under § 1396d(a) – and therefore required to be covered by EPSDT – include physician's services, inpatient and outpatient care, and prescription drugs. 42 U.S.C. §§ 1396d(a)(1), (2), (5), (12). Courts have ruled that the discretion that states may have in whether to provide coverage for certain treatments for adults is inapplicable when it comes to medically necessary treatments falling under EPSDT. See Pittman, 998 F.2d at 892; see also EPSDT Guide at 23-24 (utilization controls fairly placed on treatments for adults cannot be placed on treatment for people under 21 because of EPSDT).

States may elect not to cover experimental treatment. See Miller ex rel. Miller v. Whitburn, 10 F.3d 1315, 1318 (7th Cir. 1993). But courts have applied a restrictive definition of "experimental" to prevent states from denying medically necessary care to needy youth: whether the service is "generally accepted by the professional medical community as an effective and proven treatment for the condition for which it is being used. . . . [And] if the service or treatment is not yet generally accepted, is rarely used, novel or relatively unknown then authoritative evidence must be obtained that it is safe and effective" to require coverage. Rush v. Parham, 625 F.2d 1150, 1156 n.11 (5th Cir. 1980); see Miller, 10 F.3d at 1320 (quoting Rush, 625 F.2d at 1156); Weaver v. Reagen, 886 F.2d 194, 198-99 (8th Cir. 1989) (same); McLaughlin ex rel. McLaughlin v. Williams, 801 F. Supp. 633, 638 (S.D. Fla. 1992) (same).

C. Hormone Therapy To Treat GD In People Under 18 Is Medically Necessary

For Some Patients And Must Be Covered Under EPSDT.

The record shows that the use of pubertal suppressants to block puberty in adolescents with GD is "generally accepted" as medically necessary, safe, and "effective and proven" by practitioners treating GD in adolescents. (¶¶ 190-209.) Moreover, DOH does not dispute that pubertal suppressants may be medically necessary to treat GD in adolescents. (¶ 210.)

The record also shows that the use of cross-sex hormones in people under 18 with GD is "generally accepted" as medically necessary, safe, and "effective and proven" by practitioners treating GD in youth. (¶¶ 212-20.) DOH does not dispute that cross-sex hormones may be medically necessary to treat individuals under 18 with GD. (¶ 212.)

Defendant's stated justification for the exclusion of coverage for youth hormone therapy is that "[i]t is the policy of the New York State Medicaid program to only cover drugs that are for medically accepted indications" as defined by federal law (the "Accepted Indication Policy"), and because pubertal suppressants and cross-sex hormones do not meet that definition, coverage for these treatments is not permitted. (¶¶ 46, 222-23.) That justification fails.

The Medicaid Act permits a state to "exclude or otherwise restrict coverage of a covered outpatient drug if– (i) the prescribed use is not for a medically accepted indication (as defined in subsection (k)(6) of this section)." 42 U.S.C. § 1396r-8(d)(1)(B). The term "medically accepted indication" is defined as "any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 301 et seq.] or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(i) of this section." Id. § 1396r-8(k)(6). A "covered outpatient drug" in turn "does not include any drug . . . provided as part of, or as incident to and in the same setting as . . . (D) Physicians' services." Id. § 1396r-8(k)(3).

As an initial matter, DOH's designated representative has admitted that the Accepted

Indication Policy is optional, and that the exclusion of drug coverage for non-medically accepted indications is not a federal mandate. (¶¶ 224-25.) In other words, nothing stops New York from covering non-medically accepted indications if it so chose.

Second, even if the Accepted Indication Policy were mandatory – and it is not – its application to youth under 21 violates EPSDT. As is clear from EPSDT's plain text and case law interpreting it, coverage for medically necessary treatments *must* be provided to people under 21, even if such treatments are not covered for adults. See S.D., 391 F.3d at 590; Pittman, 998 F.2d at 891-92. Application of an optional restriction here would render the EPSDT's specific mandate to cover all categories of services, even optional ones, meaningless.

Third, relying solely on FDA approval or compendia support would exclude too wide a range of medically necessary treatments that must be provided under EPSDT. The Weaver case is instructive on this point. Weaver involved Missouri's refusal to cover the AIDS drug known as AZT beyond the uses for which it received FDA approval, which at the time was limited to certain types of AIDS patients. Weaver, 886 F.2d at 196. The Weaver court found that the status of FDA approval had no bearing on what the current medical knowledge or practice was for AIDS treatment. Id. at 198. Upon proof that practitioners were prescribing AZT to treat AIDS patients much more broadly than indicated by FDA approval, the court ordered that Missouri cover AZT for all AIDS patients whose physicians certified that AZT was medically necessary. Id. at 199-200. Similarly here, it is clear that the FDA and the compendia do not reflect the current state of medical knowledge, and cannot be used to justify denial of medically necessary treatment and compound the suffering of adolescents with GD. (¶ 226-29.)

Fourth, the "permissible restriction" related to medically accepted indications does not extend to drugs that are "provided as part of, or as incident to and in the same setting as"

physicians' services. 42 U.S.C. § 1396r-8(k)(3)(D). As a result, to the extent that any medically necessary hormone therapy is provided to people under 18 in the context of a physician visit, it must be covered by Medicaid. (Tangpricha Decl. ¶ 8.)

Because there is no genuine dispute that use of hormone therapy to treat GD in people under 18 is generally accepted by practitioners in the field, as unrebutted expert evidence shows (¶¶ 212-15, 219-20), summary judgment on Plaintiffs' Sixth Claim for Relief should be granted. See Hayden, 955 F. Supp. at 259 (granting summary judgment where expert's opinion "is supported by documentary proof and where a jury verdict rejecting that testimony would be rationally unsupported"); see also Smith v. Benson, 703 F. Supp. 2d 1262, 1276 (S.D. Fla. 2010) (granting summary judgment to Plaintiffs on EPSDT claim upon "uncontroverted" opinion of Plaintiffs' medical expert that treatment was medically necessary).

D. Gender Reassignment Surgeries Are Medically Necessary To Treat GD In Certain People Under 18 and Under 21 And Must Be Covered By EPSDT.

Any blanket ban on coverage for medically necessary treatments for people under 21 is wholly anathema to the purposes of EPSDT, which aims to prevent diagnoses discovered during youth from worsening or persisting into adulthood. The body of medical evidence is clear that leaving GD untreated into adulthood creates complications to treatment, particularly due to letting the "wrong" form of puberty take its course. (¶¶ 184-87, 193.) The opinions of Plaintiffs' medical experts bear this out, and are unrebutted. (¶¶ 179-80, 184-86.)

To be clear, Plaintiffs are not advocating for GRS for toddlers (or hormone therapy, for that matter), as Defendant may try to imply. There may be people in various stages of puberty, however, who are under 18 or 21 for whom some form of surgery is medically necessary, as determined by physicians. For example, as Dr. Olson has testified, there are instances when some form of GRS may be necessary for someone who is under 18, and there are instances when

chest surgery is necessary for female-to-male youth at younger ages. (¶¶ 184-86.)

Because § 505.2(*l*) prohibits coverage for all such procedures regardless of a person's individual circumstances, it is invalid. The Court should grant summary judgment for Plaintiffs so that § 505.2(*l*) can be brought in line with EPSDT and so that Class members under the ages of 21 and 18 can begin receiving the treatment that they desperately need.

CONCLUSION

For the reasons set forth above, Plaintiffs respectfully request that the Court grant summary judgment on Plaintiffs' First, Second, and Sixth Claims for Relief, and grant Plaintiffs such other and further relief as the Court deems just and proper.

Dated: August 28, 2015
New York, New York

Respectfully submitted,

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